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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/250,083 02/15/99 DESSEN

A GFN-5341

EXAMINER

HM12/1022

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MORAN, M

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/250 083

Applicant(s)

DESSON ET AL.

Examiner

MP WOODWARD

Group Art Unit

1631

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/11/01 & 7/31/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-29 is/are pending in the application.
- Of the above claim(s) 1-15, 17, 19 & 26-29 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 16, 18 & 20-25 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 12
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

DETAILED ACTION

Specification

The substitute specification filed September 5, 2000 has not been entered because it does not conform to 37 CFR 1.125(b) because: a marked up copy of the specification was not received.

Election/Restriction

Applicant's election without traverse of claims 16, 18 and 20-25 in Paper No. 16 is acknowledged.

Claims 1-15, 17, 19 and 26-29 are withdrawn from consideration as being drawn to non-elected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 18 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A necessary, but not sufficient, condition to practice the invention of claims 16, 18 and 20-25 is cPLA₂ of sufficient purity that a molecular model can be obtained. In the instant specification it is suggested that an x-ray crystallographic model be generated. Therefore, the specification must

present an enabling disclosure for how to obtain cPLA₂ preparations amenable to crystallization. The purported purification procedure for cPLA₂ is set forth at pages 35-36 of the specification. However, the specification affords no specific sequence of steps to permit the isolation of cPLA₂ of sufficient purity rather there is a single sentence suggesting that among the multiple steps involved were affinity and size exclusion chromatography. In the absence of a protocol whereby cPLA₂ of sufficient purity can be obtained the claims are not enabled.

A second necessary, but not sufficient, condition to practice the invention of claims 16, 18 and 20-25 are crystals of cPLA₂. As with the purification scheme the crystallization procedure set forth at page 36 is insufficient to permit reproduction of the crystals. For example no buffer from which cPLA₂ is crystallized is set forth nor the PEG 1000 or (PEG 400 and DMSO) concentrations necessary to obtain native an heavy atom-modified crystals.

Claims 20 and 23 require that one synthesize a potential inhibitor cPLA₂, however, the specification fails to set forth teachings which permit the synthesis of molecules which constitute such putative inhibitors. No specific class of molecules with the potential to act as inhibitors is described.

Claims 22 and 25 recite particular atoms or amino acids in cPLA₂ which may be involved in catalysis. The claims recite that one or more atoms of the recited groups potentially interact with inhibitors, however, the specification merely offers an invitation to experiment to determine which of

the recited sites is critical to inhibition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

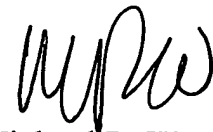
Claims 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 should have step (a) amended to recite "a model of cPLA₂ comprising a data set embodying the structure of cPLA₂."

Claim 18 is vague in that it does not set forth what cPLA₂ is binding.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Supervisory Patent Examiner Michael P. Woodward whose telephone number is (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Michael P. Woodward
Supervisory Patent Examiner
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Art Unit 1631